

## A CROSS-SECTIONAL STUDY OF PULMONARY FUNCTION TESTS IN TYPE 2 DIABETES MELLITUS AND CORRELATION WITH GLYCEMIC INDEX AND DURATION OF DIABETES

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### ABSTRACT

#### BACKGROUND

*Diabetes mellitus is a metabolic disorder of multiple etiologies characterized by chronic hyperglycemia and complicated by involvement of many organs like cardiovascular system, nervous system, renal system and respiratory system.*

#### AIMS AND OBJECTIVES

*The study was undertaken to study various pulmonary function parameters in type 2 diabetic patients and compare them with matched healthy subjects and study its association with the duration of diabetes and glycosylated hemoglobin (HbA1c).*

#### MATERIALS AND METHODS

*Pulmonary function tests (PFTs) were recorded in type 2 diabetic patients and normal healthy controls, 72 males in each group, aged 35-55 years using Medspiror (computerized spirometer). PFT parameters, which were recorded were - FVC, FEV1, FEV1%, MMEFR 25-75%, MMEFR 0.2-1.2 L, PEFR, FEV3 and MVV. PFTs of diabetic patients and controls were compared by applying student's unpaired t test. Association of PFTs with HbA1c and duration of illness in diabetic patients was analyzed by applying Pearson's correlation coefficient.*

#### RESULTS

*There was a significant decrease in FVC, FEV1 and FEV1% in type 2 diabetic patients when compared with the healthy controls, whereas the other PFT parameters, MMEFR 25-75%, MMEFR 0.2-1.2L, PEFR and MVV did not show significant changes when compared to the control group. The impairment in pulmonary function was found to be more marked with the duration of diabetes and increased levels of glycosylated hemoglobin.*

#### CONCLUSION

*The present study is suggestive of impairment in pulmonary functions (restrictive type). Also all the lung function parameters, except MMEFR 0.2-1.2 L had a positive correlation with the duration of diabetes and HbA1c (glycosylated hemoglobin).*

**KEYWORDS:** Pulmonary Function Tests, NIDDM, Type 2 Diabetes Mellitus & HbA1c

Received: Sep 08, 2019; Accepted: Sep 28, 2019; Published: Nov 11, 2019; Paper Id.: IJMPSDEC20195

### INTRODUCTION

Diabetes is one of the most common metabolic disorders with an increasing incidence and prevalence in Asian Indians.<sup>[1]</sup> Diabetes is a complex syndrome characterized by hyperglycemia secondary to deranged secretion and action of insulin. It leads to specific microvascular complications (retinopathy and nephropathy), macrovascular complications

(accelerated atherosclerosis) and a variety of other complications, like neuropathy and increased tendency to infection. According to the Diabetes Atlas 2006, published by the International Diabetes Federation, the number of people with diabetes in India is expected to rise to 69.9 million by 2025. Type 2 diabetes mellitus is the most common form of diabetes and is characterized by disorders of insulin action and insulin secretion, either of which may be the predominant feature. The chronic hyperglycemia of diabetes is associated with damage and failure of various organs, especially the eyes, kidneys, nerves, heart, respiratory system and vascular system. Various pulmonary complications have been reported in type 1 diabetes mellitus, like reduced elastic lung recoil, reduced diffusing capacity, increased incidence of viral and bacterial infections.<sup>[2]</sup> Most of the literature available on the investigations of lung functions on diabetes mellitus have reported abnormalities related to both ventilatory mechanics and pulmonary diffusion. However, less is known about the pulmonary complications in type 2 diabetes mellitus, who are on oral hypoglycemic drugs for control of diabetes and its correlation with HbA<sub>1c</sub> and duration of diabetes.

## AIMS AND OBJECTIVES

- To study and compare the pulmonary functions in subjects with type 2 diabetes mellitus/NIDDM (study group) with non-diabetic subjects (control group).
- To study the correlation of PFT parameters with glycosylated hemoglobin and duration of diabetes in type 2 diabetes mellitus (study group).

## MATERIALS AND METHODS

The present study was conducted in a tertiary hospital, in type 2 diabetic patients attending the diabetic clinic, after approval by institutional ethical review committee. The present study comprised of two groups:

**Group 1:** Study group comprised of 72 male patients of the age group 35–55 years, attending diabetic clinic and on oral hypoglycemic drugs for control of diabetes. Subjects were followed up for a duration of 1½ years.

**Group 2:** Control group comprised of 72 healthy male subjects of the age group 35–55 years. They were randomly selected from the general population. Their fasting and post meal blood sugar levels were determined.

Both the groups were non-smokers and free from any respiratory or cardiac disorders, which could affect lung functions. Informed written consent was obtained followed by a detailed personal, family history and systemic examination.

## STUDY PROTOCOL

### Anthropometric Measurements

- **Age:** was recorded from birthday by calendar to the nearest of year (< 6 months and > 6 months)
- **Height:** It was measured in cm, with the help of height measurement stadiometer.
- **Body Weight:** It was measured in kg, by portable human weighing machine.
- **Body mass index:** Was calculated by the formula BMI = Weight (in kg)/Height (in m<sup>2</sup>). All the subjects in the study had BMI above 25.

### Biochemical Parameters

The biochemical parameters were estimated in the clinical biochemistry laboratory using commercial kits adapted to auto analyser. Under all aseptic precautions, 2 ml of venous blood was collected in ethylenediaminetetraacetic acid (EDTA) bulb in all the diabetic patients. HbA1c of all the patients was estimated by ion exchange resin method by the diagnostic glycohemoglobin kits of Asritha Diotech, as per the guidelines provided.<sup>[3]</sup> HbA1c was used as an index of diabetic control over the last three months. Values over 7.5% were considered as poor glycemic control and lower than this level was considered as good glycemic control.

Fasting and postprandial blood glucose was estimated by glucose oxidase peroxidase method.<sup>[4]</sup> The oral glucose tolerance test (OGTT) was done for the control group to exclude diabetes. Only those controlled subjects with a normal fasting blood glucose of < 110 mg/dL and two hours post oral glucose of < 140 mg/dL were selected for the study. Fasting blood glucose of  $\geq 126$  mg/dL was used to define diabetes.

### Respiratory Parameters

Pulmonary function tests were done on a computerised spirometer, in a separate quiet room. This spirometer provides detailed analysis of observed and predicted values. To avoid diurnal variation, all the subjects in the study group were asked to report with light breakfast in the morning hours between 10 to 12 noon. They were asked to avoid beverages like tea, coffee and other stimulants. The technique of performing FVC (maximum inspiration followed by fast forceful expiration) was demonstrated to all subjects in standing position with the nose clip held in position. To get familiar with the procedure, self-demonstration was given and the subjects were asked to give few practice blows. Only when subjects were familiar with the procedure, three consecutive readings were obtained, out of which, one of the best was selected (based on the criteria of American Thoracic Society).<sup>[5]</sup> Following parameters were recorded on the spirometer: FVC, FEV<sub>1</sub>, FEV<sub>1</sub>%, MMEFR<sub>25-75%</sub>, MEFR<sub>0.2-1.2L</sub> and PEF. After a rest of 10 minutes, test to obtain maximum voluntary ventilation volume (MVV) was carried out. The subjects were asked to inhale and exhale as deep and as fast as possible for 12 seconds. Three consecutive readings were obtained, out of which the best was noted.

### Statistical Analysis

It was done using SPSS software (version 16.0). Results were expressed as mean  $\pm$  SD. Students unpaired 't' test was used to compare the control and diabetic group subjects. Association of PFT parameters with HbA1c and duration of illness in type 2 diabetic patients were analyzed by applying Pearson's correlation coefficient.

### Observations

**Table 1** indicates the number of subjects included in the study, duration of diabetes and levels of glycosylated hemoglobin in the controlled (healthy subjects) and study group (type 2 diabetics). There was a significant increase in HbA1c in type 2 diabetic study group as compared to control group.

**Table 1: Indicating Number of Subjects, Duration of Diabetes and HBA1c**

	Control	NIDDM/Type 2 Diabetes Mellitus
No of subjects	72	72
Duration of diabetes	-	4.47 $\pm$ 1.82
HBA1c	5.11 $\pm$ 0.30	7.62 $\pm$ 1.03 (difference is significant)

**Table 2** illustrates the anthropometric parameters in control group and type 2 diabetics. No significant difference was observed between the two groups for age, height, weight and BMI. BMI of all the subjects in the study was below 25.

**Table 2: Comparison among study Groups for Anthropometric Parameters**

Parameters	Control Mean $\pm$ SD	NIDDM/ Type 2 Diabetes Mellitus Mean $\pm$ SD	P Value	Test of Significance
Age	48.10 $\pm$ 5.62	48.54 $\pm$ 4.78	0.227	Not significant
Height	162.57 $\pm$ 6.38	162.11 $\pm$ 5.94	0.453	Not significant
Weight	56.54 $\pm$ 4.77	56.07 $\pm$ 6.99	0.204	Not significant
BMI	21.64 $\pm$ 2.27	21.65 $\pm$ 3.30	0.084	Not significant

**Table 3** shows mean  $\pm$  SD of the fasting and postprandial blood glucose levels in the controlled and type 2 diabetic subjects. There was a significant increase in both the fasting and post-meal glucose levels in the type 2 diabetic subjects.

**Table 3: Comparison of Fasting and Post Meal Blood Sugar Levels among Study Groups**

Parameters	Control Mean $\pm$ SD	NIDDM/ Type 2 Diabetes Mellitus Mean $\pm$ SD	Unpaired T Test	P Value	Test of Significance
Fasting blood sugar	83.79 $\pm$ 6.50	97.54 $\pm$ 11.50	8.831	0.000	Diff is Sig
Post Meal Blood Sugar	127.93 $\pm$ 9.85	171.42 $\pm$ 14.60	20.949	0.000	Diff is Sig

**Table 4** shows mean  $\pm$  SD of the pulmonary function parameters in the control and type 2 diabetic subjects. There was a significant decline in FVC, FEV<sub>1</sub> and FEV<sub>1%</sub> in type 2 diabetic subjects as compared to control subjects. The preserved ratio of FEV<sub>1</sub>/FVC% indicates a restrictive type pulmonary dysfunction. There was no significant difference in MMEFR<sub>25-75%</sub>, MEFR<sub>0.2-1.2 L</sub>, PEFR and MVV in type 2 diabetic subjects as compared to controlled subjects.

**Table 4: Comparison among Study Groups for Pulmonary Function Tests**

Parameters	Control Mean $\pm$ SD	NIDDM Mean $\pm$ SD	Unpaired T Test	P Value	Test of Significance
FVC	2.78 $\pm$ 0.32	2.58 $\pm$ 0.33	3.643	0.000	Diff is Sig
FEV1	2.37 $\pm$ 0.29	2.11 $\pm$ 0.27	5.503	0.000	Diff is Sig
FEV1%	84.18 $\pm$ 3.26	82.22 $\pm$ 3.44	3.499	0.001	Diff is Sig
MMEFR <sub>25-75%</sub>	3.29 $\pm$ 0.71	3.18 $\pm$ 0.37	1.240	0.217	Diff is not Sig
MMEFR <sub>2-1.2L</sub>	5.77 $\pm$ 0.77	5.62 $\pm$ 0.70	1.219	0.225	Diff is not Sig
PEFR	7.40 $\pm$ 0.72	7.37 $\pm$ 0.77	0.258	0.797	Diff is not Sig
FEV3	2.66 $\pm$ 0.34	2.63 $\pm$ 0.33	0.620	0.536	Diff is not Sig
MVV	98.49 $\pm$ 10.88	96.25 $\pm$ 10.52	1.254	0.212	Diff is not Sig

**Table 5** indicates correlation of PFT parameters with duration of diabetes and HbA1c in type 2 diabetics. All the PFT parameters showed a positive correlation with both the duration of diabetes and glycosylated hemoglobin.

**Table 5: Correlation of PFTs with Duration of Diabetes and HBA1c**

Duration of diabetes				Glycosylated haemoglobin (HBA1c)			
Parameter	Pearson Correlation	P Value	Correlation is	Parameter	Pearson Correlation	P Value	Correlation is
FVC	-0.807	0.000	Significant	FVC	-0.810	0.000	Significant
FEV1	-0.763	0.000	Significant	FEV1	-0.773	0.000	Significant
FEV1%	0.285	0.015	Significant	FEV1%	0.252	0.033	Significant
MMEFR <sub>25-75%</sub>	-0.155	0.000	Not Significant	MMEFR <sub>25-75%</sub>	-0.066	0.583	Not Significant
MMEFR <sub>2-1.2L</sub>	-0.397	0.193	Significant	MMEFR <sub>2-1.2L</sub>	-0.313	0.008	Significant

PEFR	-0.525	0.000	Significant	PEFR	-0.418	0.000	Significant
FEV3	-0.485	0.000	Significant	FEV3	-0.477	0.000	Significant
MVV	-0.455	0.000	Significant	MVV	-0.484	0.000	Significant

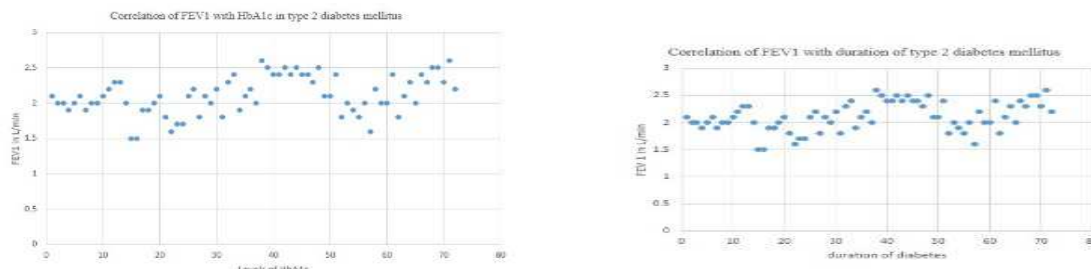


Figure 1

## DISCUSSIONS

In the present study, we observed that there was a significant decrease in FVC, FEV<sub>1</sub> and FEV<sub>1%</sub> in type 2 diabetic patients when compared with the healthy controls, whereas the other PFT parameters, MMEFR<sub>25-75%</sub>, MMEFR<sub>0.2-1.2L</sub>, PEFR and MVV did not show significant changes when compared to the control group. The decrease in FEV<sub>1%</sub> in type 2 diabetics in our study suggested that the impairment of pulmonary functions was primarily restrictive in nature.

In a meta-analysis, van den Borst, B. pooled the data of 40 studies and concluded that there is a moderate, but statistically significant, impaired lung function, which tends towards a restrictive pattern in diabetes mellitus and which was more pronounced in type 2 diabetes.<sup>[6]</sup> A similar decline in FVC and FEV<sub>1</sub> have been reported by the authors who have conducted studies in NIDDM subjects.<sup>[7, 8, 9, 10]</sup> However, the Rancho Bernardo Study refuted the association of NIDDM with pulmonary function. This might be due to the inclusion of small number of subjects in the study with severe diabetes or those with diabetes of prolonged duration. The study recommended the need to conduct more epidemiological studies to provide further information about the relationship between NIDDM and lung function.

All the type 2 diabetic subjects in the study group had a high level of fasting and postprandial blood glucose levels and increased levels of glycosylated hemoglobin as compared to the control group subjects. Levels of glycosylated hemoglobin in type 2 diabetics was  $7.62 \pm 1.03$ , which indicates poor glycemic control. There was a significant correlation of all PFT parameters, except MMEFR<sub>25-75%</sub>, with HbA1c and duration of diabetes.

Previous studies assessing the relationship between blood glucose control and pulmonary function have reported results which are not consistent.<sup>[11]</sup> However, in the Fremantle diabetes study, Davis TM *et al.* observed reduced lung volumes and airflow, which he stated was likely due to chronic complications of type 2 diabetes and the severity may be related to glycemic exposure. The study concluded that the declining lung function measures could be consistently predicted by poor glycemic control in the form of a higher mean HbA1c, follow-up HbA1c, or follow-up of fasting plasma glucose.<sup>[12]</sup> Also, A. Mohd. Khan *et al.*<sup>[13]</sup> in his study on diabetic patients, found profound impairment in pulmonary function with duration of diabetes, especially after 10 years and suggested that lower FVC and FEV<sub>1</sub>/FVC% than predicted may be related to poor glycemic control, which persisted due to longer duration of diabetes. Similar findings were also found by A. Kaparianos *et al.*<sup>[14]</sup> and M. Erfan *et al.*<sup>[15]</sup> in their study

of pulmonary functions in diabetes mellitus.

The duration of diabetes in type 2 diabetic subjects in our study was  $4.47 \pm 1.82$  years. Higher levels of HbA1c and fasting and post meal blood sugar levels in the study are suggestive of poor glycemic control in the study group population. Also, in type 2 diabetes mellitus, unlike type 1 diabetes, where there is acute onset of insulin deficiency, the exact onset of diabetes cannot be predicted. Various studies were carried out to study the association of duration of diabetes and spirometric measurements have established the existence of strong positive correlation with duration of diabetes than with metabolic control.<sup>[16, 17]</sup>

With longer duration of diabetes, the hyperglycemia may linger for a greater length of time, and this may likely increase the possibility of diabetes, affecting both the microvascular and macrovascular tissue.

Lung has abundant connective tissue and this may increase the possibility of it getting affected by hyperglycemia and thereby its inclination for non-enzymatic glycosylation of its tissue proteins. Collagen is the major connective tissue of the lung parenchyma and both qualitative and quantitative abnormalities in collagen can cause restrictive pulmonary disease<sup>(18)</sup>. The normal elastic and compliant properties of the lung require that all the connective tissue elements work in harmony and in proper spatial orientation with one another. The strength and stability of the connective tissue is provided by the cross-link formation of both collagen and elastic components and the 'stocking mesh' arrangement of these fibers.<sup>[19, 20, 21]</sup> In diabetes mellitus, one of the major mechanisms to interfere with connective tissue crosslink is the presence of increased non-enzymatic glycosylation of lysine or hydroxylysine residues due to prolonged exposure of connective tissue proteins (collagen/elastin) to hyperglycemia resulting in impairment of mechanical properties of the lung.<sup>[20]</sup>

Histopathologic evidence of lungs in diabetic subjects have revealed thickened alveolar, capillary and pulmonary arteriolar walls and with passage of time, these changes in the lungs become a cause of decrease in diffusion capacity, pulmonary dysfunction and lung function impairment.<sup>[21, 22, 23]</sup> In the present study, it was not possible to conduct diffusion studies due to practical difficulties.

Other possible contributory factors for lung impairment can be glycation of chest wall and bronchial tree proteins, autonomic and phrenic neuropathy resulting due to diabetes, thereby causing alterations in bronchial reactivity and respiratory muscle function<sup>[24]</sup> and an increased inclination to respiratory infections.<sup>[25]</sup> Also, it is known that surfactant is secreted by type II epithelial cells<sup>[26]</sup> and experimental studies in rat lung indicate that the granular endoplasmic reticulum are most dependent on insulin for normal metabolic functions.<sup>[8]</sup>

Lung has an extensive capillary bed and so it is likely to be affected by diabetic microangiopathy. The epithelial and capillary basal lamina of alveoli are significantly thicker in diabetics.<sup>[19, 27]</sup> Another mechanism whereby diabetes might be expected to worsen pulmonary function is atherosclerosis.<sup>[28]</sup>

Thus, various factors may contribute to decreasing the pulmonary compliance.

Though the findings in the study (decrease in FVC, FEV<sub>1</sub> and FEV<sub>1%</sub>) may not be clinically relevant under stable conditions, but the impairment of pulmonary functions is indicative of loss of pulmonary reserves, which may be a problem in conditions of increasing pulmonary demand like lung infection to which diabetic population is known to be more prone.

## CONCLUSIONS

The present study revealed significant decline in FVC, FEV<sub>1</sub> and FEV<sub>1%</sub> (restrictive type) in type 2 diabetic patients, which may be due to the non-enzymatic glycosylation of collagen in the lung tissue, microangiopathy and alteration in respiratory muscle function. Duration of diabetes and HbA1c levels are the major determining factors of lung pathology.

## SUGGESTIONS

It would be advisable for diabetic patients to undergo periodic spirometry test along with glycosylated hemoglobin which can be helpful to identify the susceptible diabetic patients. There is scope for further work wherein the study can be extended by including diffusion studies as part of the protocol, which could not be done due to unavailable resources.

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